UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Prevention, Pesticides
and Toxic Substances

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SUBJECT: Carbaryl: Agency Response to Comments on Phase 5 Risk Assessment; DP Barcodes: D295080; PC Code: 056801.

FROM: Jeffrey L. Dawson, Chemist/Risk Assessor
Reregistration Branch 1
Health Effects Division (7509C)

Felecia Fort, Chemist
Reregistration Branch 1
Health Effects Division (7509C)

Kit Farwell, DVM, Toxicologist
Reregistration Branch 1
Health Effects Division (7509C)

THRU: Whang Phang, PhD, Branch Senior Scientist
Reregistration Branch 1
Health Effects Division (7509C)

TO: Anthony Britten, Chemical Review Manager
Reregistration Branch 3
Special Review and Reregistration Division (7508C)

Attached is the Agency's Response to public comments provided by several organizations on the revised (Phase 5) human health risk assessment for carbaryl (D287532, March 14, 2003). Each comment is summarized and is identified by the docket identifier (OPP-2003-0101) and a suffix (e.g., -0013, 0014, etc.). The full set of comments received are available in the electronic docket (www.epa.gov/edockets). Only comments pertaining to the human health risk assessment are addressed here.

SUBMITTER / COMMENT	AGENCY RESPONSE
California Department of Food and Agriculture (OPP-2003-0101-0013)	
Carbaryl is an important tool in controlling glassy winged sharpshooter, an insect vector of a plant disease (Pierce's Disease) that can cause large acreage losses in vineyards.	EPA has discussed these comments with Tom Esser, a Special Assistant for the Pierce's Disease Program in the California Department of Food and Agriculture, most recently in September 2004. EPA has requested detailed comments on risk mitigation in the carbaryl IRED that is likely to impact the Pierce's Disease program.
Bayer Crop Science (OPP-2003-0101-0016)	
REIs for carbaryl should be based on Agriculture Reentry Task Force (ARTF) data rather than default transfer coefficients. Bayer has submitted a summary of the ARTF data and its impact on REIs.	The carbaryl risk assessment includes only the ARTF data that have been deemed acceptable based on reviews by the Agency. Recently integrated studies include: three greenhouse activity studies conducted by ARTF, a floriculture harvesting study conducted by the California Department of Pesticide Regulation and submitted by Bayer, the ARTF blackberry harvesting study, and a re-evaluation of the transfer coefficient cluster for tree crop harvesting. EPA is reluctant to use further ARTF data until data for all crop groups covered by ARTF because the data review process is still ongoing and final determinations based on these data are still incomplete. The Agency will use additional data from ARTF as reviews become available and analyses pertaining to how transfer coefficients are to be used are completed.
California Cantaloupe, Honeydew and Mixed Melon Industries (OPP-2003-0101-0017), California Melon Research Board (OPP-2003-0101-0018), Florida Cattleman's Association (OPP-2002-0101-0019), Mississippi State University (OPP-2002-0101-0021), Lawn Care Association of America (OPP-2002-0101-0022), Michigan State University (OPP-2003-0101-0023), Cranberry Institute (OPP-2003-0101-0024), MBG Marketing / Michigan Blueberry Growers Association (OPP-2002-0101-0025), Texas Vegetable Association (OPP-2002-0101-0026), Texas Citrus Florida Mutual (OPP-2003-0101-0027), Florida Citrus Mutual (OPP-2002-0101-0034), American Sugarbeet Growers Association (OPP-2003-0101-0036), Washington Tri-State University - TriCities (OPP-2003-0101-0038), U.S. Apple Association (OPP-2003-0101-0041), Washington Asparagus Commission (OPP-2003-0101-0044)	

SUBMITTER / COMMENT	AGENCY RESPONSE
Commodity groups provided various crop or site-specific comments, such as descriptions of pesticide needs, use patterns, application rates, pest pressures, cultural practices, likely occupational exposure from various activities, reentry intervals (REIs), scout exemptions and early entry activities.	EPA's crop-specific decisions and rationales for occupational uses of carbaryl are described in the IRED. Numerical risk estimates are presented in Tables 29 (applicator) and 30 (postapplication). Commodity groups who still have questions, comments or concerns based on the IRED document will be invited to contact the Agency during the formal public comment on the IRED planned for November 2004. With regard to reentry intervals, EPA considers the key activities related to crop production and also how the timing of chemical use overlaps with these activities. Scout exemptions and early entry activities are subject to the requirements of EPA's Worker Protection Standard (WPS) for entering treated areas prior to the expiration of REIs. These are supposed to be rare, and the Agency believes use of applicator-like levels of clothing and protective equipment should be health protective for these events. The WPS also describes certain non-contact activities, such as driving a combine during grain harvest, which are thought to result in no consequential exposure, and which can occur regardless of established REIs. The WPS is codified in Title 40 of the Code of Federal Regulations, Part 170. More information is available on EPA's Internet site at http://www.epa.gov/pesticides/ health/worker.htm Below are more detailed responses for two crop-specific comments (blueberries and apples): The Wild Blueberry Commission of Maine commented that EPA assumed cultural practices not relevant for REI calculation. EPA acknowledges that cultural practices asssociated with production of wild blueberries in Maine are not directly reflected in the exposure data the Agency uses routinely for exposure estimates (e.g., shovel/rake devices used for harvest of wild blueberries). However, no crop or activity-specific exposure data have ever been generated directly for wild blueberry production. Therefore, the Agency must evaluate the potential for exposures on such crops, and base its estimates on the closest reasonable approximation available. The problem is compounded for Maine blueberries because they are not treated in the same manner as other types of blueberry harvesting (e.g., common practices in New Jersey or Michigan) because the cultivars are different, as are the practices needed for production of the crop. The Agency will consider using more appropriate data if it becomes available. U.S. Apple commented that the REI for apple thinning is too long because EPA uses an overly conservative transfer coefficient for hand thinning, and that EPA should use preliminary results from an ongoing hand thinning study being developed by Bayer. Based on the currently available data, the Agency does not believe that it is overestimating exposures for apple thinners at this point in time because there is only one study available for estimating exposure to apple thinners which has been used for these calculations. Bayer Crop Sciences has funded additional exposure studies for apple thinners using carbaryl and also azinphos methyl. To date, the Agency has not yet received data for either of these studies that could be considered in the current assessment for carbaryl. The Agency may consider this information in any future modification of exposure estimates for apple thinners once the data are received and deemed appropriate for use in risk assessment.

SUBMITTER / COMMENT	AGENCY RESPONSE
Natural Resources Defense Council (OPP-2003-0101-0039)	
EPA should include carbaryl and other N-methyl carbamates in a cumulative risk assessment with the organophosphates (OPs). NRDC quoted the Science Advisory Panel as being unequivocal in their recommendation that the N-methyl carbamates and OPs be included together in a cumulative risk assessment. NRDC quoted the SAP panel: "The panel agreed unanimously with OPP's conclusion that carbamate pesticides that inhibit acetylcholinesterase should be grouped with the organophosphorus pesticides that also cause acetylcholinesterase inhibition." NRDC quoted OPP: "... OPP knows of no means to meaningfully differentiate between the consequences of AChEI by these carbamate and organophosphate compounds."	EPA is not grouping n-methyl carbamates and organophosphates for cumulative assessment at this time. The initial grouping of carbamates and OPs into a common mechanism group was just one step in the final grouping of pesticides that will undergo a cumulative risk assessment. Pharmacokinetic, pharmacodynamic, and exposure issues all need to be considered in the final grouping of a cumulative assessment group. As further clarification, the SAP report dated November 18, 1999 also said: "Although the capacity to inhibit acetylcholinesterase is an appropriate mechanism for the initial grouping of carbamates and organophosphorus pesticides, other critical factors such as potency, rates of reactivation of inhibited enzyme, recovery rates *in vivo*, and non-cholinergic effects of these compounds should be considered for the final grouping of pesticides that will undergo a cumulative risk assessment." (Emphasis added). As reported in the IRED, OPs and carbamates have differences in pharmacokinetics and pharmacodynamics and cholinesterase inhibition is by different biochemical mechanisms. As a result, there are differences in the time course of events: time to peak effect, elimination half life, duration of action, and recovery time after exposure. EPA is continuing to investigate the pharmacokinetics and pharmacodynamics of N-methyl carbamates for the cumulative assessment of these pesticides.
Natural Resources Defense Council (OPP-2003-0101-0039) [CONTINUED]	
EPA has disregarded adverse effects on developing brain structure and function, and relied on extrapolations from unpublished, uninformative data to remove the FQPA factor. NRDC said that "significant changes in some of the brain morphometric measurements were observed in offspring at the high dose". It was impossible to examine low- and mid-dose animals, as requested by EPA, because the tissues had dried.	Effects noted at the high dose were considered "minimal" and not "significant" effects. This conclusion was reached after HED very carefully evaluated the effects and conducted new statistical analyses. HED discounted a number of arguments proposed by the registrant as to why the effects should not be considered treatment related. Morphometric changes were considered by HED to be treatment related, but as likely minimum effect levels. That is, the consistent but small changes in the high dose group would likely not have been present in the mid dose group. After the re-analysis by HED, the NOAEL value of 1 mg/kg/day in the developmental neurotoxicity study remained unchanged, line G of the cerebellum was eliminated from consideration, and changes in Line F of the cerebellum were determined to be significant. As mentioned above, HED rejected the registrant arguments that the effects were not treatment related. EPA and NRDC scientists met after NRDC submitted this comment, and the information exchanged seemed to address NRDC's primary concerns.

SUBMITTER / COMMENT	AGENCY RESPONSE
Natural Resources Defense Council (OPP-2003-0101-0039) [CONTINUED]	
NRDC commented that , "In [EPA's] March 11, 2003 response [to comments], EPA reports that a two-generational study was received, and the industry re-measured the same brain morphometric data (control and high-dose only), and that, based on this, elimination of the FQPA factor is justified (Appendix A, p. 33). It is of concern to us that an FQPA factor was removed based on re-submitted industry data. Re-reading high-dose morphometric data does not compensate for the lack of data from the mid- and low-dose groups. Therefore, NRDC does not accept the claim that this is informative 'new' data."	The FQPA safety factor for carbaryl was re-evaluated for several reasons. Changes to the brain morphometric data were one of several reasons to re-visit the FQPA safety factor, but these data did not play a key role in changing the FQPA safety factor. The FQPA safety factor was re-evaluated because new data became available, specifically a two generation reproduction study in rats and new brain morphometric measurements. The toxicology database for assessing the FQPA safety factor was incomplete when HED originally recommended retaining the 10X FQPA safety factor in 1998. At that time there were no acceptable pre-natal developmental toxicity studies in rats and rabbits or a two generation reproduction toxicity study in rats (FQPA Committee document, August 27, 1998). In 2002 there were acceptable developmental toxicity studies in rats and rabbits and a two generation reproduction toxicity study in rats, and the toxicology database for assessing the FQPA safety factor was complete (FQPA Committee document, April 3, 2002). The safety factor was also re-evaluated in order to follow new approaches used by HED in evaluating the FQPA safety factor of pesticides. In addition to these new data, the Committee used a weight-of-the-evidence approach to determine the magnitude of the FQPA safety factor that differed slightly from the approach it used in 1999 and 2001. This weight-of-evidence approach included an analysis of data from different studies considered together and included 1) determination of the level of concern for the effects observed when considered in the context of all available toxicity data; and 2) identification of any residual concerns after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment of this chemical. (Guidance document, Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment. February 28, 2002)

SUBMITTER / COMMENT	AGENCY RESPONSE
Natural Resources Defense Council (OPP-2003-0101-0039) [CONTINUED]	
EPA reliance on unpublished, preliminary, uninformative cholinesterase data is unacceptable. NRDC said, "It is difficult for me to determine whether or not comparative cholinesterase data exist. The Appendix A (p. 32) implies that cholinesterase data exist, when stating that there are results from an NIEHS study that 'indicate that there is no difference in the levels at which cholinesterase inhibition occurs in pups and adults' based on measurements on gestational day 19. However, the preceding sentence implies that such data do exist, when stating that 'there was no concern for the lack of comparative data in adults and offspring for cholinesterase inhibition because no alterations in the functional observational battery (FOB) were seen in pups". *NRDC also commented that conversations with the study authors of the NIEHS study indicated that too few animals were used and that cholinesterase determinations were made of adults and fetuses, but not offspring.*	The statement from the HIARC report that there were no comparative data for cholinesterase inhibition in pups and adults was referring only to the developmental neurotoxicity study. The HIARC and FQPA Committees had cited an unpublished study from the National Health and Ecological Effects Research Laboratories, EPA, and the National Institute for Environmental Health Sciences/National Toxicology Program which was believed to show that offspring were no more sensitive than adults to cholinesterase inhibition from carbaryl. HED has since consulted with one of the principal investigators in this study, Dr. Stephanie Padilla, who said that the study was not cleared for release and should not be used. HED, therefore, agrees with NRDC that this report should not be used. However, this study was just one item that was assessed in the weight-of-evidence approach to determining the magnitude of the FQPA safety factor. Another study, which was not cited in the FQPA Committee report, supports the FQPA Committee's decision. This study, conducted by the Neurotoxicology Division of EPA's Health Effects Research Laboratory shows that adult rats were more sensitive than weanling rats to acute, oral toxicity from carbaryl. In this study, plasma and brain cholinesterase activity were inhibited to a greater degree and for longer time periods in adults than weanlings. Motor activity was decreased to a greater degree in adults than in weanling rats. (Neurotoxic potential of pesticides: Age-related effects of pesticides relevant to youth in agriculture. S. Padilla, R. MacPhail, L. Reiter. September 27, 1985.) EPA and NRDC scientists met after NRDC submitted this comment, and the information exchanged seemed to address NRDC's primary concerns.
Natural Resources Defense Council (OPP-2003-0101-0039) [CONTINUED]	
Removal of the FQPA factor requires validation, not speculation. AND EPA derives an NOAEL by extrapolation rather than observation. *[EPA is addressing these two closely related NRDC comments in one response. NRDC refers to the "significant" effects seen in morphometric measurements of the brain in high-dose female pups, and that the next lower dose was considered the NOAEL although measurements in that dose group were not conducted. NRDC contends that it is not possible to determine a NOAEL in this study.]*	This comment was addressed previously (EPA memo, Carbaryl: Agency response to comments. March 11, 2003. D286511). The effects at the high dose were considered "minimal" and not "significant" effects. Both the HIARC (March 5, 2002 and May 9, 2002) and the FQPA SF Committee (April 3, 2002) determined that it was unlikely that there would be any adverse effects on brain morphometry at the next lower dose of 1 mg/kg/day, which was 1/10th the dose at which the minimal effects were noted. Had the effects been more severe or had the dose for the high-dose group been closer to that for the mid-dose group, then it would have been prudent to apply an additional safety factor to compensate for the weakness in the data.

SUBMITTER / COMMENT	AGENCY RESPONSE
Natural Resources Defense Council (OPP-2003-0101-0039) [CONTINUED]	
Farm children are especially vulnerable to pesticide exposure, and are not adequately considered. NRDC cited studies related to farm children exposure.	EPA's most comprehensive response to date on this issue can be found in the Agency's response to objections on an imidacloprid tolerance (see http://www.epa.gov/EPA-PEST/2004/ May/Day-26/p11779.htm, Sections III D. and VII. A). In short, for carbaryl, EPA has considered the data referenced by NRDC and found that it is too limited to conclude that children in agricultural areas experience significantly higher levels of exposure than children in non-agricultural areas. In EPA's judgment, the weight of currently available evidence relating to pesticide residues in house dust or on other surfaces fails to establish that children living in agricultural areas or children living nearer to agricultural pesticide use areas experience higher exposures to pesticides than children in the general population. Similarly, biomonitoring data available for comparing the levels of pesticide exposure experienced by agricultural children with other children is fragmentary and does not show that there are significant differences between these groups. That is, it does not appear that farm children consistently receive more pesticide exposure than the groups of children (those at the upper percentile of estimated exposure) used by EPA in its current approach to assessing aggregate risk. EPA will however continue to monitor and review the results of extensive ongoing research and take appropriate steps to address any documented exposure concerns regarding children.
Natural Resources Defense Council (OPP-2003-0101-0039) [CONTINUED]	
EPA improperly relied on a confidential industry model (CARES) to assess human health risks. [Note: CARES = Cumulative and Aggregate Risk Evaluation System]	EPA received a CARES assessment completed by Bayer CropScience, the primary (data developing) technical registrant for carbaryl. EPA reviewed this submission to determine its adherence to guidelines for probabilistic assessment promulgated by the Agency. EPA did use results from this assessment when characterizing risks in the IRED document. In reviewing the submission, the Agency determined that the analysis used many of the same approaches that had been vetted in the organophosphate cumulative assessment process. The Agency's risk management decision for the populations addressed in Bayer's CARES assessment (i.e., principally children playing on treated turf) was based primarily on the results of the Agency's deterministic assessment using Its *Standard Operating Procedures For Residential Exposure Assessment* and the suburban resident biological monitoring study conducted by Bayer (MRID 45788501). The similarity in results from all three assessment strategies gives EPA increased confidence basing its decision on the deterministic assessment. Finally, with regard to public availability of the CARES model, the public can now download CARES 2.0 from the International Life Sciences Institute web site at http://cares.ilsi.org/.

SUBMITTER / COMMENT	AGENCY RESPONSE
Natural Resources Defense Council (OPP-2003-0101-0039) [CONTINUED]	
Dietary risk: EPA did not consider food purchased at farmer's markets, farm stands, "U-Pik" farms, or eaten from household gardens.	EPA does not explicitly assess potential exposures from food obtained from roadside stands or "pick-your-own" operations due to lack of data on how many people consume foods from these sources and what proportion of their individual diets is from such sources. However, EPA anticipates that a very small percentage of the U.S. population derives more than a negligible portion of their food in this manner. Moreover, some harvested crops are distributed so quickly to wholesale and retail outlets that the residues in them would be very similar to the levels in crops sold near where they are grown. Therefore, it is believed that the exposure assessment adequately accounted for food purchased at "U-Pik" farms.
Natural Resources Defense Council (OPP-2003-0101-0039) [CONTINUED]	
Dietary risk: EPA should not have used the percentage of crop treated to adjust the acute dietary risk assessment.	The FIFRA and FQPA statutes are silent on whether EPA can use percent crop treated (PCT) adjustments for acute dietary (food) risk assessments. The statutory language is constructed to place certain restrictions on the use of PCT information in chronic risk assessments. This suggests Congress was merely setting out rules for use of PCT information in these situations and not making a broader statement about the general use of this information. OPP has chosen to incorporate percent crop treated into acute probabilistic exposure estimates as well as chronic assessments for the food pathway since use of these data provide a better estimate of the range and associated probabilities of exposures. In other words, if some percentage of a crop is not treated this would lower the probability that a consumer would eat a treated commodity, but not alter the range of estimates of the residue levels on that treated commodity . EPA recognizes that the percent of a crop treated can change from year to year, and accounts for this in making estimates that are unlikely to understate the actual percent crop treated . By generally using the 99.9 th percentile of the population in estimating reasonable high-end exposure and using upper end percent crop treated forecast estimates, EPA continues to properly and appropriately account for the higher-end exposures.

SUBMITTER / COMMENT	AGENCY RESPONSE
Natural Resources Defense Council (OPP-2003-0101-0039) [CONTINUED]	
Residential risk concerns. NRDC expressed specific concerns about residential handler exposures (e.g., applicators), and residential postapplication exposures.	EPA's risk mitigation decisions and decision rationale for residential risks of concern are described in Table 25 of the IRED (handler exposures) and in Table 26 (postapplication exposures). NRDC comments focused on two postapplication exposure scenarios of concern for toddlers: carbaryl use in pet products and on residential turf. Pet use. The technical registrants are voluntarily canceling the pet uses for shampoos and dusts. An end-use registrant, Wellmark International, is providing data in support of carbaryl use as an ingredient in pet collars. Preliminary data reviewed by the Agency shows short-term MOEs exceeding the target MOE of 300 for short-term exposure. The end-use registrant also submitted for EPA review (currently pending) confirmatory data for intermediate and long-term exposure durations. Lawn use. On June 27, 2003, the carbaryl technical registrants agreed to cease production of carbaryl technical labeled for residential lawn broadcast application of carbaryl liquid formulations until EPA could consider data being submitted to refine the Agency's risk assessment for post-application exposures to toddlers. BayerCrop Science has since submitted to the Agency new pharmacokinetic data, and a method for using the data in a deterministic calculation to refine risk estimates. EPA is planning to seek independent scientific review of the information through an SAP meeting in December 2004. EPA also plans to publish for comment in October 2004 a Federal Register notice announcing the availability of the Carbaryl IRED, with errata changes and other minor amendments, including documents relevant to the Agency's current conclusions regarding the residential turf use.
Natural Resources Defense Council (OPP-2003-0101-0039) [CONTINUED]	
No appropriate exposure data exist for the following scenarios: animal grooming dust applications, dust applications in agriculture, handheld fogging for mosquito and other pest treatments, power backpack application, tree injection, drenching/dripping seedlings.	EPA agrees with NRDCs concern about the lack of available data to assess these scenarios. In October 2004, EPA plans to send a Data Call In (DCI) to the carbaryl technical registrants seeking this data.

SUBMITTER / COMMENT	AGENCY RESPONSE
Beyond Pesticides (OPP-2003-0101-0040)	
EPA does not have adequate data to lower the 10x FQPA safety factor. Beyond Pesticides commented that "For chronic duration exposures, a No Observed Adverse Effect Level (NOAEL) could not be defined in the toxicology study, so a Lowest Observed Adverse Effect Level (LOAEL) was used instead. Although the NOAEL could not be determined in the study, EPA lowered the FQPA safety factor from 10x to 3x. A 3x safety factor does not compensate for the uncertainty of not knowing the true NOAEL. One must err on the side of caution when examining the toxicological data. If a NOAEL cannot be determined, it must be assumed that at the smallest feasible dose, effects are observed. EPA must retain the 10x safety factor to adequately protect human health."	As described below, the HIARC report (May 9, 2002) adequately describes the reasons that the LOAEL from the lowest dose in the chronic dog study was believed to be close to the NOAEL value and that a 3x safety factor to derive a NOAEL value was appropriate. "The HIARC established the Chronic RfD using the LOAEL of 3.1 mg/kg/day in the chronic toxicity study in dogs. Since a NOAEL was not established in this study, an additional uncertainty factor of 3X was applied to the LOAEL (i.e, UF_L). The HIARC determined that 3X is adequate to account for the lack of a NOAEL in this case because: 1) the study was well-conducted and there are sufficient data from subchronic and other chronic studies in other species that support cholinesterase inhibition as the critical effect for Carbaryl; 2) the data indicate that the dog is more sensitive to the cholinergic effects of Carbaryl and using this species to establish the RfD provides additional protection for the effects seen in the rat (including the reproduction and developmental neurotoxicity studies); 3) the magnitude of plasma cholinesterase inhibition (12-23% decrease) seen in this study was comparable to the magnitude of inhibition (22%) seen in the 5-week study in dogs - indicating no cumulative effect following long-term exposure; 4) the cholinesterase inhibition seen in females at the LOAEL in this study was not accompanied by clinical signs (response was not judged to be severe); and 5) no inhibition was seen for any cholinesterase compartment in males at this dose (response was seen in only one sex). The HIARC concluded that the extrapolated NOAEL of 1 mg/kg/day used to establish the Chronic RfD for Carbaryl is below the NOAEL for offspring toxicity (5 mg/kg/day) in the 2-generation reproduction study and is protective of chronic dietary exposures to infants and children."
Beyond Pesticides (OPP-2003-0101-0040) [CONTINUED]	
The risk assessment fails to implement FQPA mandates for EPA to assess estrogenic potential and take action based on this potential "as is necessary to ensure the protection of public health." [FFDCA Sec. 408 (p)]	As stated in the IRED, "When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, carbaryl may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption."

SUBMITTER / COMMENT	AGENCY RESPONSE
Beyond Pesticides (OPP-2003-0101-0040) [CONTINUED]	
The prevalence of residential uses of carbaryl, potential exposure to children in the home, the number of carbaryl incidents, and children dietary needs are all factors necessitating a 10x FQPA safety factor.	The residential uses of carbaryl have been evaluated using the Agency's common methodologies. When we complete chemical assessments based on these conservative methodologies, we have not retained the 10x for exposure issues. EPA has assessed children's exposure, both from dietary exposures and residential uses. EPA's dietary assessments take into account children's increased consumption of certain foods, and the amount of these foods consumed by children relative to their body weight. Both the human health risk assessment and the IRED included a discussion of the human incident reports. Incident data suggest that the more serious incidents involve residential adults rather than children or occupational handlers, which may suggest that careless handling by homeowners is a factor. EPA assesses pesticide uses based on label rates and use directions, as well as on widespread and commonly recognized practice. The available information concerning residential use and the incident data do not suggest a widespread or common practice of misuse of carbaryl resulting in exposures of concern to children. Pesticide misuse is an important issue, and EPA seeks to address the issue through efforts such as consumer education, improved labeling and mitigation. For carbaryl, the IRED discusses several voluntary cancellations which will help reduce residential exposures, including uses mentioned by the commenter, such as aerosol products and certain pet products (dusts and shampoos).
Beyond Pesticides (OPP-2003-0101-0040) [CONTINUED]	
EPA must assess increased carbaryl residential use due to the phase out of chlorpyrifos and diazinon.	EPA is aware that the loss of chlorpyrifos and diazinon in the residential market may cause carbaryl use to increase. Carbaryl is not, however, a ready alternative to all residential pest complexes previously controlled by the other two chemicals. A more important consideration for human health risk assessment is that the key decisions related to carbaryl's use in a residential environment were based on deterministic assessments that modeled individual behaviors, and also the biological monitoring study conducted by Bayer for turf and ornamental gardens. The results of these assessments would not be impacted by market share. Bayer also submitted a probabilistic assessment for carbaryl which accounts for market share, but their assessment provided only supplemental risk characterization for EPA's decision, and incorporating additional market share would not change projected risks at the 99.9% level of exposure for households that use carbaryl.
Beyond Pesticides (OPP-2003-0101-0040) [CONTINUED]	
The golf course exposure scenario should include children.	EPA is aware that children of all ages, even very young children, routinely play golf. Children who golf and play at or near the number of holes per outing played by adults are in the 12 to 18 year old range. The Agency believes that dermal exposure is the key source of golfer exposure. Based on this, the Agency also believes that children in this 12 to 18 age group, on a per pound of body weight basis, would have exposure levels similar to those for adults because dermal skin surface area changes relative to body weights (which differ for children of various ages). The Agency also believes that its assessments are protective of younger children, even though they may have other sources of exposure, such as mouthing, because they just do not spend the same amount of time on a golf course that an adult would. This is evidenced by the number of Junior golfer training programs and 3, 6, or 9 hole round specials that are available for children at many courses.

SUBMITTER / COMMENT	AGENCY RESPONSE
Beyond Pesticides (OPP-2003-0101-0040) [CONTINUED]	
"Average or typical" rate information for some residential products exceeds maximum label application rates by up to a factor of two. If real usage exceeds label rates, all risk assessments must reflect these exposure numbers.	EPA does not have information supporting the view that real usage rates exceed label rates. If Beyond Pesticides has such information, it did not provide specific examples. We ask that Beyond Pesticides review the carbaryl IRED and determine if they still have concerns for specific application rates EPA used for residential mitigation decisions. We will then respond more directly. It is possible that Beyond Pesticides has misconstrued a statement in the HED risk assessment. The HED risk assessment notes in the residential section that: "Label maximum use rates and use information specific to residential products served as the basis for the risk calculations. If additional information, such as average or typical rates, were available, these values were used as well in order to allow risk managers to make a more informed risk management decision. Average application rates were available from the SMART meeting and BEAD's Quantitative Usage Analysis (QUA). These data indicate that in most cases, average application rates differ from maximum application rates by a factor of approximately two. The average application rates identified from the studies conducted by Bayer CropScience were also considered." (Emphasis added.) EPA acknowledges that this statement is less clear than it could be, but the context makes it clear that EPA uses label maximum use rates as well as average application rate information if it is available to provide risk managers with additional information upon which to base their decisions. In most cases, average application rates were two times lower than the maximum label rate.

SUBMITTER / COMMENT	AGENCY RESPONSE
Farmworker Justice Fund, et. al. (OPP-2003-0101-0046)	
EPA underestimates occupational risk and proposes inadequate risk mitigation measures. EPA has underestimated the duration of worker exposure, both in terms of hours worked per day and days per year. Many handlers and field workers routinely work 10-12 hour days for 6 or 7 days/week. US Department of Labor's National Agricultural Worker Survey (2000) reports that 56% of crop workers works 31 to 50 hours/week and 15% worker more than 50 hours/week. For postapplication workers, EPA has assumed 10 days/year for private growers and 30 days/year for commercial farmworkers. Many farmworkers are on crews receiving greater exposure; for example, apple harvesters in Virginia, New York, and Washington state routinely work 6 days/week for 2 to 3 months. Apple thinners in Washington typically work 6 days/week for 6 weeks, and citrus harvesters often work 6 days/week for 4 months.	The nature of the results calculated for post-application workers has to be considered in the context of the inputs for overall assessment. Farmworker risks are calculated using three basic inputs that are multiplied together to calculate exposure estimates. The first is the DFR or dislodgeable foliar residue, which in this case reflected maximum application rates for crops and typical rates when available. Maximum rates are not used to that great an extent and typical rates still represent a central tendency estimate. The next factor is the transfer coefficient, which represents the exposures associated with specific crops and activities. Current methods used by the Agency are based on data from the Agricultural Reentry Task Force (ARTF), but to address still unresolved uncertainties (e.g., accuracy of handwash technique) the Agency uses results for workers wearing short-sleeved shirts instead of long-sleeved shirts (as required by WPS) which purposefully increases exposure levels and accounts for any underestimation related to hand monitoring methods. Finally, the duration of exposure is the third key input. The Agency has considered the NAWS data and a survey conducted by the ARTF which evaluated worker activities in different crops and regions of the country. The Agency acknowledges the durations noted above in the comment and has found similar results. The Agency uses an 8 hour day which is found to be a typical full day for most surveys of this nature. This, however, should be put in context with the overall results generated when maximum application rate DFRs are used with purposefully conservative transfer coefficients and the 8 hour day. Indeed, biological monitoring data also support the supposition that overall exposure estimates using this technique tend to be conservative. EPA believes that its current calculations are protective, but realizes that many uncertainties still remain about this methodology and is currently engaged in efforts to better ascertain the true distribution of exposure for post-application workers. These efforts include development through ILSI of a probabilistic worker exposure methodology; completion of the ARTF project with final transfer coefficient determinations; comparative analyses with additional biomonitoring data; and evaluation of basic methods such as addressing the uncertainties related to passive dosimetry and the handwash technique.
Farmworker Justice Fund, et. al. (OPP-2003-0101-0046) [CONTINUED]	
Farmworker exposure continues after the end of the workday because workers do not have access to showering and changing facilities until after they arrive home. A survey of Yakima Valley farmworkers showed that only half the workers bathed and changed clothes as soon as they got home.	EPA agrees that farmworker exposures can exceed the typical workday, but also believes that potential exposures calculated in its current risk assessment approach are conservative (protective), and accounts for these types of exposures. Of course, the issue also goes beyond risk assessment methodologies and extends to the need for improving implementation of the Worker Protection Standard (40 CFR 170) hygiene requirements for reducing such exposures.

SUBMITTER / COMMENT	AGENCY RESPONSE
Farmworker Justice Fund, et. al. (OPP-2003-0101-0046) [CONTINUED]	
EPA should not rely on data from the Agricultural Reentry Task Force (ARTF) until these data have been independently validated.	EPA disagrees with this comment. Several issues merit consideration. First, ARTF was formed in response to an Agency DCI in 1995 and a committee comprising of Agency scientists as well as representatives from Health Canada and the California Department of Pesticide Regulation have been advising the ARTF on scientific issues since its inception. This arrangement ensures consistency among North American regulatory Agencies and in this regard is no different than other FIFRA task forces. In no way has ARTF been involved with final Agency determinations about the use of the data or other key issues related to policy. The second major issue is that ARTF is not yet complete and many data and analytical issues are still being considered, including much effort on characterizing exposure estimates. Third, the monitoring techniques used by ARTF are based on Agency guidelines in-use since the early 1980s. These guidelines have been peer reviewed by the FIFRA SAP and have been reevaluated since their inception. They are available as a draft from the Agency (http://www.epa.gov/opptsfrs/home/guidelin.htm). The techniques used for guideline studies are based on published literature techniques by noted researchers such as Durham and Wolfe, Fenske, and Popendorf. Techniques have also been adopted from the World Health Organization. In essence, the ARTF has been conducting a number of guideline studies and has been seeking protocol and review from the Agency on the studies conducted. ARTF also has conducted its own peer review in which noted researchers such as Fenske and Popendorf participated, as well as representatives from other organizations such as commodity groups. It is believed the ARTF asked worker advocacy groups to participate in this process, but none participated.
Farmworker Justice Fund, et. al. (OPP-2003-0101-0046) [CONTINUED]	
EPA must recalculate the cancer risk for handlers and postapplication workers; none of the cancer risks should be allowed to exceed 1 x 10^{-6}. The FQPA of 1996 articulates the level of cancer risks acceptable to the public; this should also be applied to farm workers.	EPA uses a 1 x 10^{-6} (1 in 1 million) risk estimate as a threshold to identify potential cancer risks of concern. Risks in the 10^{-6} range or less (e.g., 10^{-7} or 10^{-8}) are considered negligible and not of concern to the Agency. If risk estimates are greater than 10^{-6} (e.g., 10^{-5} or 10^{-4}), EPA will first attempt to refine its risk assessment to obtain a more accurate characterization of the risk. If the level of concern is still exceeded, OPP will consider a variety of measures for reducing the risk to a level at or below the level of concern. For occupational scenarios, EPA must also consider the benefits of a use in its risk management decision. If occupational cancer risk estimates remain in the 10^{-4} to 10^{-6} range despite practicable, cost effective mitigation measures, EPA will consider whether benefits of the use warrant the estimated risks. EPA is confident that the conservative methods used in its cancer assessment are adequately protective against unreasonable adverse effects to human health in the 10^{-6} to the 10^{-4} range. EPA generally doesn't grant new registrations or allow the continued registrations of existing uses which yield cancer risks greater than 10^{-4} (e.g., 10^{-8}) because EPA believes such risks usually outweigh benefits and thus will cause unreasonable adverse effects.
Farmworker Justice Fund, et. al. (OPP-2003-0101-0046) [CONTINUED]	
EPA needs to disclose carbaryl chronic health effects (carcinogenicity, reproductive risks) on product labels.	EPA approves labels for products after completing a risk assessment which evaluates all manner of potential health effects including those that can occur in an acute sense as well as those that may occur over a much longer term (e.g., chronic health effects). The Agency does not add references to specific health effects through product labeling outside of signal words (e.g., "Caution") that are based on acute toxicity. This approach has been longstanding and is based on the concept that risk assessments are considered protective for all manner of potential health effects.

SUBMITTER / COMMENT	AGENCY RESPONSE
Farmworker Justice Fund, et. al. (OPP-2003-0101-0046) [CONTINUED]	
Evidence of increased risk of neurotoxicity puts farm worker children at risk.	The information available now does not indicate that farmworker children have significantly increased exposures when compared to levels in the general population. The Agency's approach to this issues is outlined in more detail in EPA's response to a petition from NRDC. See also an earlier response in this document concerning farm children exposure and http://www.epa.gov/fedrgstr/EPA-PEST/2004/May/Day-26/p11779.pdf for further information.
Farmworker Justice Fund, et. al. (OPP-2003-0101-0046) [CONTINUED]	
EPA overestimates the value of PPE (50% protection with coveralls, 90% with gloves). Also, handlers do not always benefit from PPE because it is not provided, it is not clean or in good repair, or it is too hot to wear.	Most exposure estimates for common agricultural application methods (e.g., groundboom or airblast applications) are based on monitoring of workers wearing gloves or additional layers of clothing. In cases where direct monitoring data are not available, a protection factor of 50 percent for coveralls and 90 percent for gloves has been used. The coverall factor of 50 percent is a central tendency estimate derived from an analysis of Pesticide Handler Exposure Database (PHED) values which compared the protectiveness of clothing layers. The 90 percent factor was also derived from PHED estimates using a similar approach for gloves. These results considered with the uncertainties of the data are believed to yield typical to conservative estimates of exposure. EPA would also consider additional data as it becomes available. EPA is also concerned about compliance issues related to the implementation of the Worker Protection Standard (40CFR 170) with regard to protective clothing and equipment. EPA welcomes any suggestions from interested parties on how to better ensure label requirements for such devices are followed. The Agency would also consider other viable options for reducing exposures, such as cost effective and workable engineering options, or administrative approaches that may put fewer requirements on individual workers to reduce their exposures.
Farmworker Justice Fund, et. al. (OPP-2003-0101-0046) [CONTINUED]	
EPA's use of central tendency data significantly underestimates risk to the most highly exposed workers. Further, EPA has underestimated risk by using typical or average application rates rather than maximum rates.	Please refer to the first part of the response to the **Farmworker Justice Fund, et. al. (OPP-2003-0101-0046)** where the comment starts with "*EPA underestimates occupational risk and proposes inadequate risk mitigation measures. EPA has underestimated the duration of worker exposure, both in terms of hours worked per day and days per year.*" Also please refer to the response to the **Beyond Pesticides (OPP-2003-0101-0040)** comment that starts with "*Average or typical rate information for some residential products exceeds maximum label application rates by up to a factor of two.*"

SUBMITTER / COMMENT	AGENCY RESPONSE
Farmworker Justice Fund, et. al. (OPP-2003-0101-0046) [CONTINUED]	
EPA does not have adequate data to lower the 10x FQPA safety factor. EPA has not considered reports of carbaryl poisonings. Carbaryl represents a significant source of pesticide exposure to young children because of its common use around homes; therefore, EPA should retain the 10x FQPA safety factor based on the level of exposure.	The residential uses of carbaryl have been evaluated using an Agency method based on monitoring data (i.e., SOPs For Residential Exposure Assessment), which EPA believes is sufficiently conservative (i.e., protective) that it does not need to retain the 10x safety based on exposure issues. Also, please refer to the responses above that pertain to the application of the 10x factor for additional information. EPA had also discussed human poisoning incidents in the carbaryl risk assessment and the IRED. As noted earlier, the incident data suggest that the more serious poisoning incidents are for adult residential exposures rather than child or worker exposure, which may suggest that careless handling by adult applicators is a factor.
Florida Legal Services, Inc. (OPP-2003-0101-0047 and -0048) [CONTINUED]	
Florida Legal Services Inc. Comment: 21 citrus harvesters hospitalized on April 9, 2003, after picking oranges treated with carbaryl 8 days prior to harvesting. Florida Department of Agriculture Services collected soil, leaf, and fruit samples on April 9 and confirmed that carbaryl residue was present. Florida Legal Services is concerned that EPA underestimates post application worker risk to carbaryl and that current labeling does not adequately protect workers.	The Agency does not believe that this incident is directly related to a labeled use of carbaryl because, given what is known about the field conditions, worker activities, the toxicity of carbaryl, and the carbaryl residues detected by the state of Florida in the groves being harvested, carbaryl residues alone on the citrus trees would be insufficient to account for the severity of effects reported by the workers. The same is true regarding the results of cholinesterase testing administered by emergency room staff. Nor have there been prior reports of incidents of this magnitude despite many years of carbaryl use on citrus, including use at higher application rates. For this reason particularly it is hard to conclude that a labeled use was a principal cause of the effects reported. We are concerned about the effects reported from this incident, and in response to a request from Farmworker Justice, we are further investigating this incident in light of a decision by a Florida administrative judge regarding a workman's compensation claim made by one of the harvesters who became ill on April 9, 2003. EPA is consulting with regional staff who are most familiar with the incident, and we will consider any additional information which may become available.

October 26, 2004 (12:09pm)

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